



6-10-04

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EXPRESS MAIL NO.: EV 346 811 122 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Carrara et al. Confirmation No.: 5916
Application No.: 10/798,111 Group Art Unit: 1614
Filing Date: March 10, 2004 Examiner: To Be Assigned
For: METHODS AND FORMULATIONS FOR Attorney Docket No.: 88066-7900
TRANSDERMAL OR TRANSMUCOSAL
APPLICATION OF ACTIVE AGENTS

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to applicant's duty of disclosure under 37 C.F.R. § 1.56, enclosed are copies of seventy-six (76) references for the Examiner's review and consideration. The references are listed on the enclosed Form PTO-1449. It is respectfully requested that the references be made of record in this application by the Examiner's completion and return of the Form PTO-1449.

For the purpose of convenience, Applicants respectfully draw the Examiner's attention to the following nine references: (1) US 6,503,894; (2) US 2002/0183296; (3) US 2003/0022877; (4) US 20030050292; (5) US 2003/0139384; (6) US 2003/0232072; (7) US 2004/0002482, (8) US 5,891,462; and (9) WO 02/11768. References (1) through (7) are directed to a testosterone gel formulation, reference (8) is directed to a estrogen and progestin combination gel formulation, and reference (9) is directed to a transdermal formulation comprising permeation enhancers. The aforementioned references are believed to be more relevant than the remaining seventy-one references submitted herewith.

No fee is believed to be due for the filing of this statement as it is being submitted prior to an initial office action for this application. Should any fees be required, however, please charge such fees to Winston & Strawn LLP Deposit Account No. 50-1814.

June 8, 2004
Date

Respectfully submitted,
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202-371-5904

LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

ATTY. DOCKET NO.:

88066-7900

APPLICATION NO.:

10/798,111

APPLICANT:

Carrara et al.

FILING DATE:

March 10, 2004

GROUP:

1614

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	1	4,082,881	4-4-78	Chen et al.	424	241	
	2	4,315,925	2-16-82	Hussaiin et al.	424	239	
	3	4,383,993	5-17-83	Hussaiin et al.	424	239	
	4	4,390,532	6-28-83	Stuttgen et al.	424	240	
	5	4,537,776	8-7-85	Cooper	514	424	
	6	4,863,970	9-5-89	Patel et al.	514	784	
	7	5,071,657	12-10-91	Oloff	424	486	
	8	5,128,138	7-7-92	Blank	424	449	
	9	5,178,879	1-12-93	Adekunle et al.	424	484	
	10	5,232,703	8-3-93	Blank	424	449	
	11	5,238,933	8-24-93	Catz	514	236.2	
	12	5,371,005	12-6-94	Fujishiro et al.	435	190	
	13	5,602,017	2-11-97	Fujishiro et al.	435	190	
	14	5,629,021	5-13-97	Wright	424	489	
	15	5,660,839	8-26-97	Allec et al.	424	401	
	16	5,665,560	9-9-97	Fujishiro et al.	435	11	
	17	5,716,638	2-10-98	Touitou	424	450	
	18	5,731,303	3-24-98	Hsien	514	183	
	19	5,798,242	8-25-98	Fujishiro et al.	435	190	
	20	5,831,035	11-3-98	Timms	530	389.1	
	21	5,855,920	1-5-99	Chein	424	568	
	22	5,891,462	4-6-99	Carrara	424	449	
	23	5,904,931	5-18-99	Lipp	424	449	
	24	5,968,919	10-19-99	Samour	514	177	
	25	6,008,192	12-28-99	Al Razzak et al.	514	11	
	26	6,060,077	5-9-00	Meignant	424	434	

	27	6,096,733	8-1-00	Lubkin	514	182	
	28	6,153,216	11-28-00	Cordes	424	449	
	29	6,180,803	1-30-2001	Piasco et al.	552	150	
	30	6,214,374	4-10-01	Schmirier et al.	424	449	
	31	6,284,234	9-4-01	Niemiec	424	78.07	
	32	6,309,843	10-30-01	Timms	435	7.1	
	33	6,319,913	11-20-01	Mak et al.	514	179	
	34	6,440,454	8-27-02	Santoro et al.	424	449	
	35	6,444,234	9-3-02	Kirby et al.	424	725	
	36	6,476,012	11-5-02	Hochberg	514	182	
	37	6,497,897	12-24-02	Hidaka et al.	424	449	
	38	6,503,894	1-7-03	Dudley	514	178	
U.S. PUBLISHED PATENT APPLICATIONS							
	39	2001/0023261	9-20-01	Ryoo	514	772	
	40	2001/0033870	10-25-01	Luo	424	688	
	41	2002/0183296	12-5-02	Dudley et al.	514	177	
	42	2003/0181430	9-25-03	Gray et al.	514	170	
	43	2003/0022877	1-30-03	Dudley	514	177	
	44	2003/0050292	3-13-03	Dudley	514	177	
	45	2003/0139384	7-24-03	Dudley	514	177	
	46	2003/0232072	12-18-03	Dudley et al.	424	449	
	47	2004/0002482	1-1-04	Dudley et al.	514	169	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YESNO
	48	FR 2518879	12-30-81	France (with abstract)			X
	49	EP 0250125 B1	9-18-91	EP			
	50	EP 0325613 B1	9-8-93	EP			
	51	EP 0409383 B1	4-6-94	EP			
	52	EP 0435200 B1	7-12-95	EP			
	53	EP 785211 A1	7-23-97	EP			
	54	EP 785212 A1	7-23-97	EP			

	55	EP 0491803 B1	7-20-99	EP				
	56	FR 2776191	9-24-99	France				
	57	EP 0804926 B1	10-27-99	EP				
	58	EP 0655900 B1	3-15-00	EP				
	59	EP 0719538 B1	11-8-00	EP				
	60	EP 0814776 B1	7-4-01	EP (with abstract)			X	
	61	EP 0643963 B1	11-14-01	EP (with abstract)			X	
	62	EP 0868187 B1	12-5-01	EP				
	63	EP 0859793 B1	2-13-02	EP				
	64	EP 1089722 B1	5-22-02	EP				
	65	EP 0802782 B1	2-5-03	EP				
67 FOREIGN PUBLISHED PATENT APPLICATIONS								
	66	WO 92/08730	5-29-92	Laboratoire Theramax SAM Assignee				
	67	WO 94/06437	3-31-94	Laboratoire Theramax SAM Assignee				
	68	JP 09176049	7-8-97	Suzuki et al. (with abstract)			X	
	69	WO 97/03676	2-6-97	Cabo et al. (with abstract)			X	
	70	WO 97/34607	9-27-97	Ludwig				
	71	WO 98/37879	9-3-98	Hsieh				
	72	WO 99/24041	5-20	Cellegy Pharmaceuticals, Inc.				
	73	WO 99/48477	9-30-99	Laboratoire Theramax SAM Assignee (with abstract)			X	
	74	WO 99/20257	4-29-01	Beier et al.				
	75	WO 02/11768	2-14-02	Antares Pharma IPL AG				
	76	WO 02/22132	2-21-02	Laboratoire Theramax SAM Assignee (with abstract)			X	
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)								
EXAMINER				DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

EXPRESS MAIL LIST

To:
Commissioner for Patents
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Alexandria, VA 22313-1450



The following items listed below are being filed herewith with the USPTO on June 8, 2004.

Express Mail No. EV 346 811 122 US			
Attorney Docket No.	Appln. Serial No./ Patent No.	Items - Documents filed on <u>June 8, 2004</u>	Patent Fees- Acct. #50-1814
88066-7900	10/798,111	Information Disclosure Statement, PTO 1449 Form, 76 refs.	none

*Please acknowledge receipt of these items as received by returning
the enclosed postcards with the date of receipt of June 8, 2004*

NY:868111.6